It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions, or by children, wherein its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of the user, since its labeling bore no warning against use by children for whom, by reason of its large proportion of alcohol, it would be especially unsuitable; its labeling bore no warning against use in case of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, whereas, by reason of its content of a laxative drug such as rhubarb, it would be dangerous when used in such circumstances; and it bore no warning against frequent or continued use which might result in the establishment of dependence upon laxatives to move the bowels.

On January 7, 1943, Banfi Products Corporation, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of and in form satisfactory to the Food and Drug Administration.

959. Misbranding of Special SC Pink Tablets. U. S. v. 3 Drums of Special SC Pink Tablets. Product relabeled and ordered released to claimant. (F. D. C. No. 8428. Sample Nos. 4628–F to 4630–F, incl.)

On September 29, 1942, the United States attorney for the Middle District of Tennessee filed a libel against 3 drums containing a total of approximately 140,000 Special SC Pink Tablets at Nashville, Tenn., alleging that the article had been shipped in interstate commerce on or about February 19, April 25, and June 23, 1942, by Charles H. Dietz, Inc., from St. Louis, Mo.; and charging that it was misbranded.

Analyses of samples showed that the article consisted essentially of acetanilid, potassium bromide, laxative plant drugs, and cinchonidine sulfate.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, since there were no directions. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions, or by children, wherein its use might be dangerous to health, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; that frequent or continued use of the article might result in dependence on a laxative; and that the article was not to be given to children. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users, since the labeling failed to warn that frequent or continued use of acetanilid might be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug, and that not more than the recommended dosage was to be taken.

On October 9, 1942, the product having been relabeled and the claimant, the Gattis Chemical Co., Nashville, Tenn., having paid costs of the proceedings, the product was ordered delivered to the claimant.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH*

960. Adulteration of sulfanilamide tablets. U. S. v. 3,000 Bottles of Sulfanilamide Tablets. Consent decree of condemnation. Product ordered released under bond for segregation and destruction or reprocessing of the contaminated portion. (F. D. C. No. 8962. Sample No. 18441–F.)

Examination of a sample of this product showed that most of the tablets were covered with live mold, a species of Aspergillus.

On December 9, 1942, the United States attorney for the Eastern District of New York filed a libel against 3,000 bottles, each containing 1,000 tablets, of sulfanilamide at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce on or about November 18, 1942, by the Maltbie Chemical Co., Newark, N. J.; and charging that it was adulterated in that it consisted in whole or in part of a filthy substance.

On December 26, 1942, the Maltbie Chemical Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be sorted according to codes and the portion

*For bacterial contamination see Nos. 970–977, 985, 986.

found contaminated either destroyed or reprocessed. Any of the product so reprocessed was to be further examined and, if not fit for human or medical use, to be destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

961. Adulteration of Dr. Fenton's Necrocide Special Prescription No. 2 and misbranding of Dr. Fenton's Neumoade Special Prescription No. 1, Special Prescription No. 4, Diarrhostringent Special Prescription No. 8, Special Prescription No. 11, and Ovotone. U. S. v. Lois Swarzentruber and Venita Smith (Dr. Fenton's Vigortone Co.). Pleas of guilty. Fines, $100 and costs. (F. D. C. No. 6473. Sample Nos. 38909–E, 38910–E, 38919–E, 58422–E, 58423–E, 58425–E.)

Dr. Fenton's Necrocide Special Prescription No. 2 exceeded its own declared standard of strength. The labeling of the other veterinary products here involved bore false and misleading therapeutic claims and, with the exception of Dr. Fenton's Neumoade Special Prescription No. 1, failed to give the common or usual names of the active ingredients. Dr. Fenton's Neumoade Special Prescription No. 1 and Diarrhostringent Special Prescription No. 8 did not bear proper statements on their labels in regard to the quantity of contents.

On April 12, 1943, the United States attorney for the Northern District of Iowa filed an information against Lois Swarzentruber and Venita Smith, trading as Dr. Fenton's Vigortone Co., Cedar Rapids, Iowa, alleging shipments on or about January 7 and 20, and February 18, 1941, from the State of Iowa into the State of Minnesota of various quantities of the above-named drugs, one of which, the "Dr. Fenton's Necrocide Special Prescription No. 2," was adulterated and the remainder of which were misbranded.

Analysis of the Neumoade Special Prescription No. 1 showed that it consisted essentially of copper sulfate, Epsom salt, naphthalene, small proportions of iodide, chromate, silica compounds and plant material including capsicum and anise.

It was alleged to be misbranded in that certain statements appearing in its labeling which represented and suggested that, when used as directed, it was an antiseptic, antiferment, expectorant, resolvent, antipyretic, alterative, and sedative, were false and misleading since, when used as directed, it was not an antiseptic, antiferment, expectorant, resolvent, antipyretic, alterative, or sedative. It was alleged to be misbranded further in that the label affixed to its container failed to bear a statement of the quantity of the contents of the container in terms of weight, measure, or numerical count.

Analysis of the Necrocide Special Prescription No. 2 showed that it contained not less than 50.6 percent of copper sulfate in addition to Epsom salt, small proportions of methylene blue, plant material including capsicum, an iodide, and a dichromate compound.

It was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain not more than 25 percent of copper sulfate, whereas it contained not less than 50.6 percent of copper sulfate.

Analysis of the Special Prescription No. 4 showed that it consisted essentially of Epsom salt, copper sulfate (5.36 percent, sodium chromate, charcoal, and plant material including capsicum and anise.

It was alleged to be misbranded in that certain statements appearing in its labeling which represented and suggested that, when used as directed, it was a heart stimulant, a stomachic, an alterative, a resolvent, a deobstruent, and a diuretic; that another drug, "Dr. Fenton's Santonin Powder No. 7," would be efficacious in the removal of large and small roundworms infesting the stomach and small intestines of hogs and pigs; and that another drug, "Vigortone," would increase the vigor and tone of the system, were false and misleading since the drug, when used as directed, was not a heart stimulant or a stomachic, alterative, resolvent, deobstruent, or diuretic, and the other drugs named would not be efficacious for the purposes claimed.

Analysis of the Diarrhostringent Special Prescription No. 8 showed that it consisted essentially of charcoal, carbonate salt, brownish water–soluble organic material, copper sulfate 0.93 percent, and a small proportion of Epsom salt.

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*See also Nos. 953, 954.